Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Acidex Oral Suspension, Sodium Alginate 500mg, Sodium Bicarbonate 267mg, Calcium Carbonate 160mg/10ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml dose contains:

Sodium Alginate	500 mg
Sodium Bicarbonate	267 mg
Calcium Carbonate	160 mg

Excipients with known effect
Each 10 ml dose contains 143 mg sodium, 15.0 mg ethyl parahydroxybenzoate (E214), 5.50 mg propyl parahydroxybenzoate (E216) and 2.5 mg butyl parahydroxybenzoate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Suspension
Aniseed flavoured pink suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the management of gastric reflux, reflux oesophagitis, hiatus hernia, heartburn (including heartburn of pregnancy) and similar gastric distress.

4.2 Posology and method of administration

Posology

Adults and children over 12 years: 10-20 ml (Two to four 5 ml spoonfuls) after meals and at bedtime. The maximum daily dose is 80 ml.

Children under 12 years: Should only be given on medical advice.

Children 6 – 12 years: 5-10 ml (One to two 5 ml spoonfuls) after meals and at bedtime. The maximum daily dose is 40 ml.

Children under 6 years of age: Not recommended.

Special patient groups

Elderly: No dosage modification is required in this age group.

Hepatic Impairment: No modifications necessary.

Renal Insufficiency: Caution if highly restricted salt diet is necessary (see section 4.4).

Method of Administration

For oral administration.

Duration of treatment

If symptoms do not improve after seven days, the clinical situation should be reviewed.

4.3 Contraindications

Hypersensitivity to the active substance or any of the excipients listed in section 6.1, including ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoate (E216) and butyl parahydroxybenzoate (see section 4.4).

4.4 Special warnings and precautions for use

As with all medicines, it is recommended to limit the treatment duration as much as possible. If symptoms do not improve after seven days, the clinical situation should be reviewed.

This medicinal product contains 286.5 mg (12.45 mmol) sodium per 20 ml dose, equivalent to 14.3 % of the WHO recommended maximum daily intake for sodium. The maximum daily dose of this product is equivalent to 57.2 % of the WHO recommended maximum daily intake for sodium. This product is considered high in sodium. This should be particularly taken into account for those on a low salt diet (e.g. in some cases of congestive heart failure and renal impairment).

Calcium: Each 20 ml dose contains 320 mg of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

Contains parahydroxybenzoates (E214 and E216) which may cause allergic reactions (possibly delayed).

As with other antacid products, taking Acidex can mask the symptoms of other more serious, underlying medical conditions.

Consult your doctor if you are over 40 years and have never suffered with heartburn and acid indigestion before.

4.5 Interaction with other medicinal products and other forms of interactions

Due to the presence of calcium and carbonates, a time-interval of 2 hours should be considered between Acidex intake and the administration of other medicinal products, especially tetracyclines, fluoroquinolones, iron salts, thyroid hormones, chloroquine, biphosphonates, and estramustine. See also 4.4.

4.6 Fertility, pregnancy and lactation

Pregnancy:
Clinical studies in more than 500 pregnant women as well as a large number of data from post-marketing experience indicate no malformative nor feto/ neonatal toxicity of the active substances. Acidex can be used during pregnancy, if clinically needed.

Lactation /breastfeeding:
Pre-clinical investigations have revealed alginate has no negative effect on parental or offspring fertility or reproduction. No effects of the active substances have been shown in breastfed newborns/infants of treated mothers. Acidex can be used during breast-feeding.

Fertility:
Clinical data do not suggest that Acidex has an effect on human fertility.

4.7 Effects on ability to drive and use machines

Acidex has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions have been ranked under headings of frequency using the following convention: very common (1/10), common (1/100 and <1/10), uncommon (1/1000 and <1/100), rare (1/10,000 and <1/1000), very rare (1/10,000) and not known (cannot be estimated from the available data).

System organ class	frequency	Adverse Event
Immune System Disorders	Very rare	Anaphylactic and anaphylactoid reactions Hypersensitivity reactions such as urticaria.
Respiratory, Thoracic and Mediastinal Disorders	Very rare	Respiratory effects such as bronchospasm.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance Website: www.hpra.ie.

4.9 Overdose

Symptoms:
The patient may experience abdominal discomfort and may notice abdominal distension.

Management:
In the event of overdose symptomatic treatment should be given.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD); **ATC Code:** A02BX

On ingestion Acidex Oral Suspension reacts with gastric acid to form a raft of alginic acid gel having a near neutral pH and which floats on the stomach contents effectively impeding gastro-oesophageal reflux. In severe cases the raft itself may be refluxed into the oesophagus in preference to the stomach contents and exert a demulcent effect.

5.2 Pharmacokinetic properties

The mode of action of Acidex Oral Suspension is physical and does not depend on absorption into the systemic circulation.

5.3 Preclinical safety data

No preclinical findings relevant to the prescriber have been reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer
Sodium Hydroxide (E524) (For pH adjustment)
Saccharin Sodium (E954)
Ethyl parahydroxybenzoate (E214)
Propyl parahydroxybenzoate (E216)
Butyl parahydroxybenzoate
Isopropyl Alcohol
Erythrosine Colour (E127)
Star Anise Oil
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25^{o}C. Do not refrigerate.

6.5 Nature and contents of container

Type III amber glass bottles with pilfer proof caps and tamper evident screw caps, in pack sizes of

100ml, 150ml, 200ml, 250ml, 300ml and 500ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Shake well before use.

7 MARKETING AUTHORISATION HOLDER

Pinewood Laboratories Ltd,
Ballymacarbry
Clonmel
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0281/075/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 June 1998

Date of last renewal: 26 June 2008

10 DATE OF REVISION OF THE TEXT

November 2021